1. PURPOSE

1.1. This procedure establishes the requirements for submissions to Office of Human Research.

2. POLICY

2.1. Applications submitted for IRB review must contain sufficient information to allow the IRB to make the determinations required by DHHS and FDA regulations.

2.2. Application materials submitted to the OHR must be current versions of IRB application documents such as the human research study application form, or other applicable IRB forms and are reviewed by staff to determine that:

2.2.1. Submission forms contain required signatures from:
   2.2.1.1. Principal Investigator;
   2.2.1.2. Department Chair;
   2.2.1.3. MFA required signatures;
   2.2.1.4. If one of these individuals is unable to sign, the documents may be submitted from that individual’s email address with a statement regarding why they are unable to physically sign the documents.

2.2.2. All required protocol and regulatory information has been provided;

2.2.3. All GW required information has been provided including:
   2.2.3.1. CITI Training completion certificates within the previous two years for all research team members

2.3. The Principal Investigator (PI) or the principal contact will be notified when an application does not contain required material. The PI or principal contact is responsible for submission of requested information to OHR staff. The PI or principal contact must respond to requests from OHR staff for additional information within 30 days. The PI or principal contact may request a one-time 30 day extension period to provide the required information.

2.4. An application, for which a response has not been received within the 30 day period, or the 30 day extension period, will be withdrawn from review and consideration.

2.5. In cases where an application is withdrawn due to lack of a response from the PI or principal contact, a new application with complete study materials must be submitted to initiate the review process. No exceptions will be made.